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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,530	Applicant(s) WILKES ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 02, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,23-32,67-71 and 81-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,23-32,67-71,83 and 90-93 is/are allowed.
- 6) ☒ Claim(s) 82, 84-89, and 94 is/are rejected.
- 7) ☒ Claim(s) 81 and 94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed September 02, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Applicant's interview summary for the July 21, 2004 interview has been accepted.
3. The cancellation of claims 1-19, 22, 33-66, 72-80, and addition of claims 81-94 have been acknowledged.
4. Claims 20, 21, 23-32, 67-71, and 81-94 are examined on the merits.
5. Claims 20, 21, 23-32, 67-71, 83, and 90-93 are allowable.
6. NON-FINAL OFFICE ACTION.

OBJECTIONS

7. Claims 81 and 94 are objected to because of the following informalities: Claim 81 begins with "--" and claim 94 ends with "--" which have been interpreted as a typographical errors. Appropriate correction is required.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 85 and 87-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10. Claim 85, lines 1-2, recites a method for compensating for drift in spectroscopic, spectrometric, and chromatographic fingerprint spectra. While, the rest of the claim is directed to measuring generic “fingerprint spectrum” which causes the claim to be vague and indefinite because it is unclear whether spectroscopic, spectrometric, or chromatographic fingerprint spectra is being measured individually or all together. Clarification of the metes and bounds is required. Claims 87 and 88 are rejected for being dependent from claim 85.

11. Claims 87 and 88 recites the limitation "the multiple signals" in line 1. There is insufficient antecedent basis for this limitation in the claim.

12. Specific to claim 89, Applicant uses the abbreviations of “CI” and “APCI” in line 2. Abbreviations in claims are vague and indefinite unless accompanied by the full name, usually in parentheses.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 86-88 and 94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER.

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15. Claim 86, lines 1-2, and claims 87 and 88, line 1, recite the limitation of “multiple signals”, which has not been found in the pointed support. It is noted that Example 2 (page 29-32) and Figure 1 in the instant specification disclose “three hypothetical mass spectra” as directed to ion signal appearing in a fingerprint spectrum. Page 15, lines 23-24, discloses “fingerprint spectra...relative concentrations of biomolecules.” Pages 18-19 disclose the database construction. However, the pointed to support does not provide written basis support for the limitation of “multiple signals” as recited in claims 86-88.

16. Claim 94, line 2, recites “¹⁹F” which has not been found in the pointed to disclosure.

CLAIM REJECTIONS - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim 85, 87, and 88 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Acheson et al. (1993).

RESPONSE TO ARGUMENT

19. Applicant’s argument that the spectra data of Acheson et al. is contrary to the ordinary meaning of the word “spectra alone” has been fully considered and found to be unpersuasive. It is noted that the Merriam-Webster definition provided by Applicant to support said argument discloses a plurality of definitions for the term “spectra” wherein definition 2b is consistent with the disclosure of Acheson et al. For example, definition 2b defines “spectra” as “kinds of organism associated with a particular situation (as an environment) or

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susceptible to an agent (as an antibiotic)” which is consistent with the type of spectra cited in Acheson et al. Further, due to the vague and indefinite issue of claim 85 as discussed above, the limitation of “spectroscopic, spectrometric, and chromatographic fingerprint spectra” has been interpreted reasonably broad.

20. Acheson et al. discloses a method for comparing the expression level of SLT-I B-subunit (fingerprint spectra) from microorganisms *V. cholerae* (first microorganism) to *E. coli* (second microorganism) grown in the presence (first environmental factor effecting the metabolic state) or absence (second environmental factor effecting the metabolic state) of IPTG (Abstract etc.). It is noted that microorganisms of similar class and genus cited above are metabolically similar, and *E. coli* and *V. cholerae* are of different species.

21. *V. cholerae* and *E. coli* are grown in cultures present of IPTG (first environmental factor) (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §), as in instant claim 85, lines 4-5.

22. The concentration of SLT-I B-subunit protein (fingerprint spectra) from *E. coli* and *V. cholerae* cultured under the first environmental factor is summarized in Tables 1 and 2, as in instant claim 85, lines 6-8.

23. The concentration of SLT-I B-subunit protein (fingerprint spectra) from *E. coli* cultured in the absence of IPTG (second environmental factor) is summarized in Tables 1 and 2 (page 1102), as in instant claim 85, lines 9-11.

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24. Figure 3, Table 1, and Table 2 illustrate the derived relationship of *E. coli* (second microorganism) being cultured under the first and second environmental factors (page 1101), as in instant claim 85, lines 12-14.

25. Acheson et al. reasons that expression of SLT-I B subunit from *V. cholerae* might be constitutive (expectation) as demonstrated in *E. coli* TB1 and wishes (expectation) to investigate whether this would be true as well for the B subunit of SLT-I (page 1103, column 2, lines 41-51).

26. With the expectation of SLT-I B subunit being constitutive expressed in *V. cholerae* above, Acheson et al. applies the derived relationship from the *E. coli* (second organism) by changing (transform) the culturing conditions of *V. cholerae* (first organism) in the presence of IPTG (first environmental factor) to the absence of IPTG (second environmental factor) for constitutive expression (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §, and Tables 1-2). *V. cholerae* cultured in the absence of IPTG results in a higher concentration (compensating) of SLT-I B-subunit due to SLT-I B-subunit being constitutively expressed as expected (page 1103, column 2, lines 47-50, Figure 4, and Tables 1 and 2), as in instant claim 85, lines 15-19.

27. Acheson et al. discloses the submission of the expected fingerprint spectrum of *V. cholerae* into Tables 1 and 2 (database and multiple signals) wherein the data in the related tables are classified by organism names (keys) (page 1102, Tables 1 and 2). Figures 3 and 4 disclose multiple signals of optical density as being transformed data in Tables 1 and 2, as in instant claims 87 and 88.

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CLAIM REJECTIONS - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 82, 84, 85, 87, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acheson et al. (1993) taken with Cebolla et al. (1995).

RESPONSE TO ARGUMENT

31. Applicant's argument directed to Acheson et al. has been addressed above.

32. Acheson et al. discloses the limitations to claims 85, 87, and 88 as discussed above.

33. Further, the method of Acheson et al. comprises culturing microorganisms in 5 ml of LB medium, then, the cultures are divided in half (batch), and IPTG is added to one of the

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cultures (library) (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §), as in instant claim 82, lines 11-12.

34. However, Acheson et al. does not disclose the limitation of the second set of environmental factors differ in temperature as in claim 82, lines 12-14, and claim 84, lines 12-13.

35. Cebolla et al. discloses an improvement for increasing the expression of luciferase in *E. coli* due to changes in temperature or IPTG (first set of environmental factor). The method of Cebolla et al. is directed to cultures grown at 42°C which gave values of luciferase activity that were 30 to 300-fold higher than those in cultures grown at 30°C (second set of environmental factor) (Abstract etc. and page 664, column 2, lines 17-23), as in instant claim 82, lines 12-14, and claim 84, lines 12-13.

36. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement of Cebolla et al. cited above and utilize said improvement to increase the production SLT-I B-subunit protein (biological fingerprint spectra) as taught by Acheson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Cebolla et al. to increase the production of SLT-I B-subunit protein expression as taught by Cebolla et al. and Acheson et al.

CONCLUSION

37. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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38. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

39. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

41. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
11/8/04


MICHAEL P. WOODWARD
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